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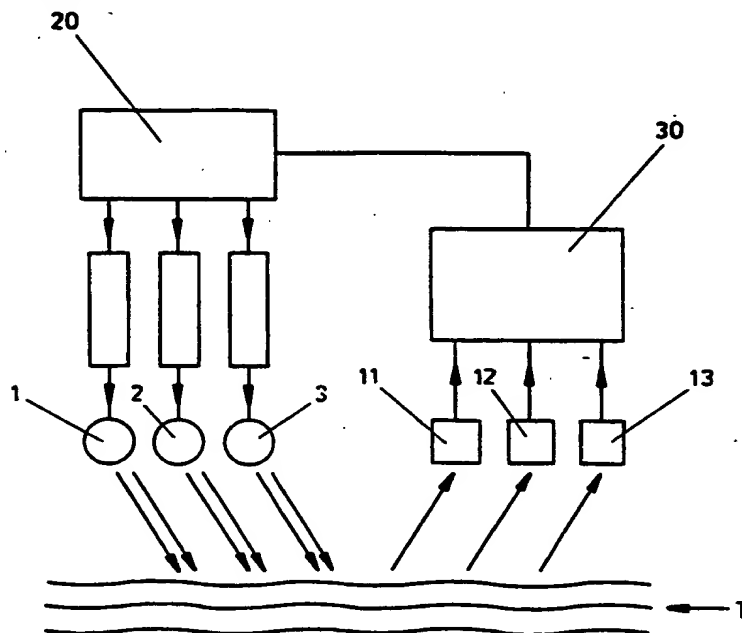
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(21) International Application Number: PCT/GB93/01630 (22) International Filing Date: 2 August 1993 (02.08.93) (30) Priority data: 9216431.8 1 August 1992 (01.08.92) GB (71) Applicant (for all designated States except US): UNIVERSITY COLLEGE OF SWANSEA [GB/GB]; Singleton Park, Swansea, West Glamorgan SA2 8PP (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): PARKER, Dawood [GB/GB]; Whitland Abbey, Whitland, Dyfed SA34 0LG (GB). (74) Agent: GIBSON, Stewart, Harry; Urquhart-Dykes & Lord, Business Technology Centre, Senghennydd Road, Cardiff CF2 4AY (GB).			(81) Designated States: AU, CA, GB, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: OPTICAL MONITOR (OXIMETER, ETC.) WITH MOTION ARTEFACT SUPPRESSION



(57) Abstract

An optical device, particularly for pulse rate and/or blood oxygen saturation monitoring, comprises a light source (1, 2, 3) emitting light at three different wavelengths, and a photodetector (11, 12, 13) for receiving the light after transmission through or reflection within living tissue (T) to produce signals corresponding to the intensities of the respective wavelengths received by the photodetector. The arrangement is such that the quiescent (or "DC") levels in the three output signals are substantially equal. A signal processor forms two signals representing the differences between two different pairs of the three outputs from the photodetector, to eliminate variations (motion artefact) due to movement of the subject. The two difference signals are further processed to extract the AC components in the photodetector outputs, from which pulse rate and blood oxygen saturation can be determined.

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OPTICAL MONITOR (OXIMETER, ETC.) WITH MOTION ARTEFACT SUPPRESSION

This invention relates to an optical monitoring or measuring device with motion artefact suppression.

Medical instruments are being developed which use non-invasive optical techniques. As is well known in the art, these instruments suffer interference due to patient movement, motion artefact.

For example it is known, in order to measure blood oxygen saturation, to provide a device which passes light through the human finger and monitors the output signal of a photodetector of this device continuously. Movement of the subject leads to changes in the light path and hence to variations in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (e.g. oxygen in the blood), and changes in received light intensity caused by variations in the light path due to movement of the subject.

Motion artefact is a significant problem in pulse oximeters, and can render these devices inoperative for up to 40% of the monitoring period in certain clinical applications. The problem is common to all optical monitoring devices and is particularly severe in critical health care applications, where continuous monitoring is essential.

We have now devised an optical measuring or monitoring device which is able to suppress the effects of motion artefact.

In accordance with this invention, there is provided an optical measuring or monitoring device which comprises light source means for emitting one or more light beams which includes light of a plurality of different wavelengths, photodetector means for receiving said light beam or beams after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means, the arrangement being such that the quiescent (or "DC") signal levels corresponding to the

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different wavelengths bear a predetermined relationship with each other, and signal processing means for processing the output signals from the photodetector means to cancel out variations due to motion artefact and to provide an output
5 representing a parameter to be measured or monitored and substantially unaffected by motion artefact.

For example, in a pulse oximetry device, light of two or more wavelengths is passed through or reflected within living tissue. At each wavelength, there is a fixed "DC"
10 intensity of light received by the photodetector, with a pulsatile "AC" component (caused by arterial pulsation) superimposed thereon.

Theoretically, and as confirmed by experiment, variations in signal output due to motion artefact (changes in
15 source-to-tissue and photodetector-to-tissue coupling) are proportional to the respective "DC" signal level. Thus, if the DC intensity of light at the photodetector were doubled, for instance by doubling the output of the light source, a given degree of mechanical disturbance to the device would produce
20 double the motion artefact variation in the detector output signal. Thus if the DC signals are equal at the different wavelengths, the amplitude of the motion artefact signal components will be the same for all those wavelengths.

Normally a pulse oximeter uses two wavelengths and the
25 signal processing unit processes the signals from the photodetector, corresponding to these two wavelengths, to provide a measure of pulse rate or blood oxygen saturation. In accordance with this invention, such a pulse oximeter uses three wavelengths: the signal processing unit processes the
30 three signals from the photodetector firstly to cancel out the motion artefact and then to determine the pulse rate and/or blood oxygen saturation.

In general, where a device normally uses n different wavelengths of light and processes the n corresponding output
35 signals from the photodetector to determine the value of the parameter being measured or monitored, in accordance with this invention the device will use an additional wavelength ($n + 1$) wavelengths altogether, so that the motion artefact can be cancelled out.

Preferably high accuracy readings are made by the controller of each of the three sources via a single sensor and a single hardware conversion block. From these readings, three difference signals are produced. Because these (AC) difference
5 signals have reduced motion artefact signal and directly reflect the different absorption levels in the tissue, they can be used in combination as indicators of the oxygen saturation level.

Preferably additional real time digital filtering of
10 the signals is used to reduce 50/60Hz components and to correlate input signals to improve noise rejection.

The input channels may be continuously monitored by the processor to ensure that the effects of component aging or temperature drifting are eliminated.

15 Preferably most of the signal processing is performed in software so the costs of the unit is low and there is no requirement for very accurate hardware matching.

An embodiment of this invention will now be described by way of example only and with reference to the accompanying
20 drawings, the single figure of which is a diagrammatic block diagram of a device in accordance with this invention.

Referring to the drawing, there is shown a pulse oximetry and blood oxygen saturation monitoring device. The device comprises three LED's 1,2,3 emitting different
25 wavelengths of light for transmission through or reflection from within living tissue, indicated schematically at T. The device further comprises photodetectors 11,12,13 for receiving each of the transmitted or reflected light beams. The device includes a control means 20, arranged to adjust the power
30 applied to the LED's, to give a "DC" signal level, in the outputs from the photodetectors 11,12,13, which is equal for all three wavelengths: this can be achieved very accurately. Then:

$$\begin{aligned} \text{OAC } \lambda_1 &= \text{AC } \lambda_1 + \text{MA} \\ \text{OAC } \lambda_2 &= \text{AC } \lambda_2 + \text{MA} \\ \text{OAC } \lambda_3 &= \text{AC } \lambda_3 + \text{MA} \end{aligned}$$

35

in which:

the OAC's are the observed AC signals from the photodetector, the AC's are the true AC signals, and MA is the motion artefact.

The device further includes a signal processor 30, in which:

OAC λ_1 is subtracted from OAC λ_2 , giving $AC\lambda_1 - AC\lambda_2$; and

OAC λ_2 is subtracted from OAC λ_3 , giving $AC\lambda_2 - AC\lambda_3$

In this manner, the motion artefact signals are subtracted out. There is a known relationship between the values of $AC\lambda_1$ and $AC\lambda_2$ and $AC\lambda_3$ of the general form :

$$\frac{AC\lambda_1 + K_1}{AC\lambda_2 + K_2} = K_4 \cdot \frac{AC\lambda_2 + K_2}{AC\lambda_3 + K_3} \quad \text{Equation 1}$$

in which the K's are known constants for the three wavelengths used. The signal processing unit then extracts the original AC components in accordance with the following:

$$\text{Let } K_5 = OAC\lambda_1 - OAC\lambda_2 = AC\lambda_1 - AC\lambda_2 \quad \text{Equation 2}$$

$$\text{Let } K_6 = OAC\lambda_2 - OAC\lambda_3 = AC\lambda_2 - AC\lambda_3 \quad \text{Equation 3}$$

$$\text{Let } A_1, A_2 \text{ and } A_3 \text{ equal } AC\lambda_1, AC\lambda_2 \text{ and } AC\lambda_3$$

$$20 \text{ From equations 2 and 3 : } A_1 = K_5 + A_2 \quad \text{Equation 4}$$

$$\text{and } A_3 = A_2 - K_6 \quad \text{Equation 5}$$

Replacing A_1 and A_3 in equation 1 using Equations 4 and 5 :

$$\frac{K_5 + A_2 + K_1}{A_2 + K_2} = K_4 \cdot \frac{A_2 + K_2}{A_2 - K_6 + K_3} \quad \text{Equation 6}$$

25 Cross-multiplying Equation 6 :

$$(K_5 + A_2 + K_1) \cdot (A_2 - K_6 + K_3) = K_4 (A_2 + K_2)^2 \quad \text{Equation 7}$$

Multiplying out the first pair of brackets in Equation 7 :

$$A^2 + (K_5 + K_1 - K_6 + K_3) A_2 + [(K_5 + K_1) (K_3 - K_6)] = K_4 A_2^2 + 2K_4 \cdot K_2 \cdot A_2 + K_4 \cdot K_2^2 \quad \text{Equation 8}$$

Rearranging Equation 8 to quadratic form :

$$(K4 - 1) \cdot A2^2 + (2K4 \cdot K2 + K6 - K3 - K5 - K1) A2 + K4 \cdot K2^2 - [(K5 + K1) (K3 - K6)] = 0 \quad \text{Equation 9}$$

Let the first term in Equation 9 = a

5 Let the second term in Equation 9 = b

Let the third term in Equation 9 = c

$$A2 = AC\lambda 2 = \frac{-b \pm \sqrt{b^2 - 4ac}}{2a}$$

and from Equations 4 and 5 : $AC\lambda 1 = K5 + AC\lambda 2$

10 and $AC\lambda 3 = AC\lambda 2 - K6$

Since K1, K2, K3 and K4 are fixed and known for the three wavelengths in use and K5 and K6 are measured, the processing unit is able to recover the three original "AC" components.

15 It may readily be shown that, where F is a simple function :

$$\%SAO2 = F \cdot \frac{\frac{AC\lambda 1}{DC\lambda 1}}{\frac{AC\lambda 2}{DC\lambda 2}}$$

20 for a two wavelength oximetry system.

For a three wavelength system, this modifies by direct analogy to :

$$25 \quad \%SaO2 = F \cdot \frac{\frac{AC\lambda 1}{DC\lambda 1}}{\frac{AC\lambda 2}{DC\lambda 2}} + K4 \cdot \frac{\frac{AC\lambda 2}{DC\lambda 2}}{\frac{AC\lambda 3}{DC\lambda 3}}$$

wherein K4 has the same value as previously.

This effectively takes the mean of two wavelength pairs
30 to obtain the blood oxygen saturation % Sa O2.

Since the DC levels are the same in this case, the formula simplifies to :

$$\%SaO2 = F \cdot \frac{AC\lambda 1}{AC\lambda 2} + K4 \cdot \frac{AC\lambda 2}{AC\lambda 3}$$

With the "DC" level equalisation in the three light channels and the motion artefact signals therefore identical, it is theoretically possible to null out the motion artefact entirely. In practice, under many circumstances, the motion
5 artefact signals differ from each other by 5 to 20% implying a degree of rejection of between 20 and 5 times. How close this figure is to 0% depends on the severity of the physical disturbance causing the artefact, and probably on the sensor design. The light source at all wavelengths are point sourced,
10 that is they originate as far as their path through the medium is concerned at a single point.

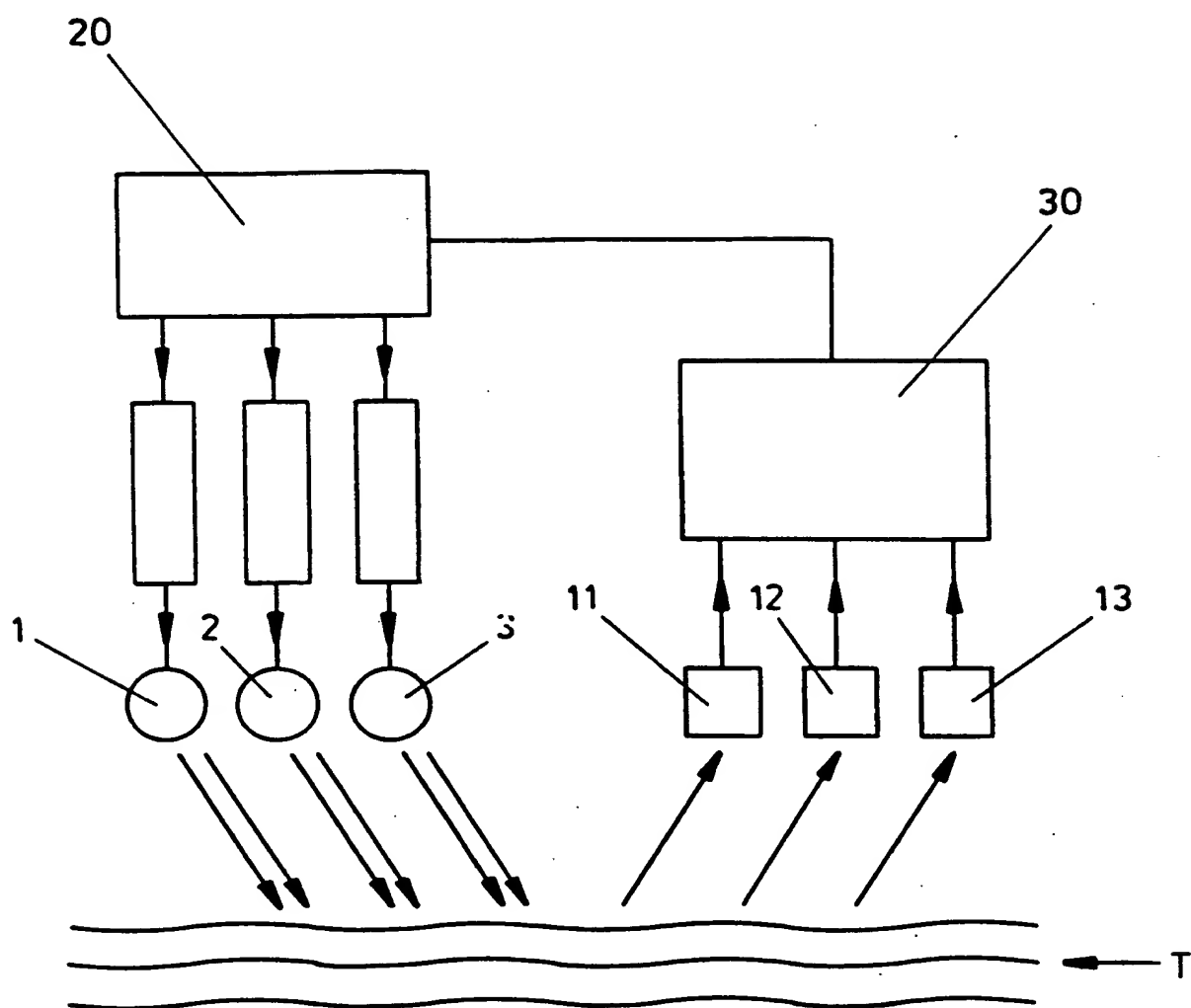
The configuration of the light sources is constrained by the physical dimensions of the sources, i.e. they are as close as is physically possible. Alternatively, a light guide
15 method may be used to make all light sources originate from a single point.

Claims

- 1) An optical measuring or monitoring device which comprises light source means (1,2,3) for emitting one or more light beams which include light of a plurality of different wavelengths, photodetector means (11,12,13) for receiving said light beam or beams after passing through or being reflected within living tissue (T) and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means (11,12,13), the arrangement being such that the quiescent (or "DC" signal levels corresponding to the different wavelengths bear a predetermined relationship with each other, and signal processing means (30) for processing the output signals from the photodetector means (11,12,13) to cancel out variations due to motion artefact and to provide an output representing a parameter to be measured or monitored and substantially unaffected by motion artefact.
- 2) A device as claimed in claim 1 in which said quiescent (or "DC") signal levels in the outputs from the photodetector means, corresponding to different said wavelengths of light, are all substantially equal to each other.
- 3) A device as claimed in claim 2, in which the signal processing means (30) is arranged to form two signals representing the differences between two different pairs of three outputs from the photodetector means (20), corresponding to three different said wavelengths of light.
- 4) A device as claimed in claim 3, in which the signal processing means (30) is further arranged to process said two difference signals to extract the AC component of at least one output from the photodetector means (20).
- 5) A device as claimed in claim 4, in which the signal processing means (30) is further arranged to determine blood oxygen saturation of the living tissue (T) from ratios of two different pairs of said AC components extracted from three outputs of said photodetector means (20), corresponding to

three different said wavelengths of light.

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FIG. 1

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INTERNATIONAL SEARCH REPORT

Internal 1 Application No
PCT/GB 93/01630

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61B5/00 A61B5/024

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,88 01147 (PHYSIO-CONTROL CORP.) 25 February 1988 see page 5, line 27 - page 7, line 12 see page 20, line 3 - page 21, line 23; figures 1-27 ---	1
X	EP,A,0 286 142 (SUMITOMO ELECTRIC INDUSTRIES LTD.) 12 October 1988 Y see page 3, line 14 - page 4, line 7; figures 1-7 ---	1 2
Y	EP,A,0 102 816 (NELLCOR INC,) 14 March 1984 see page 10, line 19 - page 13, line 8; figures 1-16 --- -/--	2

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A	EP,A,0 303 502 (NATIONAL RESEARCH DEVELOPMENT CORP.) 15 February 1989 see the whole document ---	1
A	US,A,4 266 554 (K.HAMAGURI) 12 May 1981 see the whole document ---	1,3
A	US,A,4 819 752 (M.P. ZELIN) 11 April 1989 see the whole document ---	1,2
A	EP,A,0 479 322 (SPACELABS INC.) 8 April 1992 see abstract; figures 1-10 ---	1
P,A	US,A,5 190 038 (M.J.R. POLSON ET AL.) 2 March 1993 see column 3, line 55 - column 4, line 32; figures 1-9 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-8801147	25-02-88	US-A- 4819646 AU-B- 606830 AU-A- 7718587 CA-A- 1300397 DE-A- 3785123 EP-A, B 0261789 JP-T- 1502237 US-A- 4892101	11-04-89 14-02-91 25-02-88 12-05-92 06-05-93 30-03-88 10-08-89 09-01-90
EP-A-0286142	12-10-88	JP-A- 63252239 US-A- 4867557	19-10-88 19-09-89
EP-A-0102816	14-03-84	JP-A- 59160445	11-09-84
EP-A-0303502	15-02-89	GB-A, B 2208709 JP-A- 1153139 US-A- 4955379	12-04-89 15-06-89 11-09-90
US-A-4266554	12-05-81	JP-C- 1412117 JP-A- 55024004 JP-B- 62016646	27-11-87 20-02-80 14-04-87
US-A-4819752	11-04-89	NONE	
EP-A-0479322	08-04-92	US-A- 5055671 CA-A- 2052682 US-A- 5225672	08-10-91 04-04-92 06-07-93
US-A-5190038	02-03-93	NONE	